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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,643	04/07/2006	Michelle Cayouette	564462004100 7609 EXAMINER	
45975 VERENILIM C	7590 01/07/2008 C/O MOFO S.D.	•		
12531 HIGH B			SWOPE, SHERIDAN	
SUITE 100 SAN DIEGO, CA 92130-2040			ART UNIT	PAPER NUMBER
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			MAIL DATE	DELIVERY MODE
			01/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	10/530,643	CAYOUETTE ET AL.			
Office Action Summary	Examiner	Art Unit			
·	Sheridan L. Swope	1652			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE!	I.  lely filed  the mailing date of this communication.  D (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on <u>07 Ar</u>					
· <u>-</u>	<u> </u>				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under E	х рапе Quayle, 1935 С.D. 11, 45	3 O.G. 213.			
Disposition of Claims					
4)  Claim(s) See Continuation Sheet is/are pending 4a) Of the above claim(s) is/are withdraw 5)  Claim(s) is/are allowed. 6)  Claim(s) is/are rejected. 7)  Claim(s) is/are objected to. 8)  Claim(s) See Continuation Sheet are subject to	vn from consideration.	ement.			
Application Papers					
9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the confidence of Replacement drawing sheet(s) including the correction of the oath or declaration is objected to by the Examiner.	epted or b) objected to by the Edrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)	o□	(DTO 442)			
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO/SB/08)          Paper No(s)/Mail Date</li></ol>	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa	te			

Continuation of Disposition of Claims: Claims pending in the application are 1,27,33,40,45,48,57,60,98,100,106,116,126,131,141,173-175,180,185,190,196,198,202,204-206,212-214 and 218-222.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,27,33,40,45,48,57,60,98,100,106,116,126,131,141,173-175,180,185,190,196,198,202,204-206,212-214 and 218-222.

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## **DETAILED ACTION**

Claims 1, 27, 33, 40, 45, 48, 57, 60, 98, 100, 106, 116, 126, 131, 141, 173-175, 180, 185,

190, 196, 198, 202, 204-206, 212-214, and 218-222 are pending.

## Election/Restrictions

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claim 98, in part, and Claims 1, 27, 40, 45, 57, and 106, drawn to a polynucleotide encoding a protease.

Group II, Claim 48, drawn to a transgenic organism comprising a polynucleotide encoding a protease.

Group III, Claim 98, in part, and Claims 60, 175, 180, 185, 190, 196, 198, 202, 204, 212, 213, 218, 219, 220, 221, and 222 drawn to a protease polypeptide and use thereof to make a composition.

Group IV, Claim 100, drawn to an antibody to a protease polypeptide.

Group V, Claim 116, drawn to a computer-based analysis system.

Group VI, Claim 126, drawn to a PCR method for isolating a polynucleotide encoding a protease.

Group VII, Claims 131 and 141, drawn to a method for mutating a polynucleotide encoding a protease.

Group VIII, Claims 173 and 173, drawn a method of hydrolysis using a protease.

Group IX, Claim 205, drawn to a method for treating animal waste using a protease.

Group X, Claim 206, drawn to processed waste.

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Group XI, Claims 214, drawn to a method for dissociating tissue.

For each of Inventions XI above, restriction to one or more of the following subinventions is also required under 35 USC 121. Therefore, election is required of one of Inventions I-XI <u>and</u> one or more of the following, as indicated.

If any of Inventions I, II, V, VI, or VII is elected, also elect one of the sequences listed in Claim 1.

If any of Inventions III-V or VIII-XI is elected, also elect one of the sequences listed in Claim 60.

If Invention II is elected, also elect one of: Non-human animal Plant Seed

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: The technical feature linking Groups I- XI appears to be that they all relate to proteases. However, proteases were well known in the art. For example, Tsujibo et al, 1996 teach a proteinase having 56% identity with SEQ ID NO: 4, which anticipates Claim 1. Therefore Groups I- XI share no special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Furthermore, the products of Groups I-V and X do not share a special common structural and functional feature while, the methods of Groups VI-IX and XI do not use the same reagents or produce the same results. In addition, the methods of Groups I-V and X. Accordingly, Groups I- XI are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept. In addition, the sequences of Claim 1 do not share a special common structural and functional feature. Likewise, the sequences of Claim 60 do not share a special common structural and functional feature.

Searching more than one of Groups I-XI would represent a burden on the Office for the following reasons. Because the products of Groups I-V and X do not share a special structural and functional feature, a search for any one said product would not encompass a search for any other said products. Thus, a search for more than one of the products of Groups I-V and X would be a burden on the Office. A search for any one of the methods of Groups VI-IX and XI would not encompass a search for any other said methods because the methods do not share a special technical feature of steps and products used, or results produced. Thus, the search for more than one of Groups VI-IX and XI would be a burden on the Office. A search of any one of the products of Groups I-V and X would not encompass a search of any of the methods of Groups VI-IX and XI or vice versa, because said methods are not the only methods of making or

using said products. Thus, a search of any one of the products of Groups I-V and X with any of the methods of Groups VI-IX and XI would be a burden on the Office.

These inventions lack Unity of Invention for the reasons given above. Furthermore, each invention has acquired a separate status in the art due to their recognized divergent subject matter and, thus, searching more than one invention would be a burden on the Office. Therefore, restriction for examination purposes, as indicated, is proper.

Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of a invention and sub-invention(s) to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. 821.04, In re Ochiai, and In re Brouwer). Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right, if the amendment is presented prior to final rejection or allowance, whichever is earlier. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. To be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

## Final Comments

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D. Art Unit 1652

HERIDAN SWOPE, PH.D. PRIMARY EXAMINER